



The Use of Animals in Research

Our Haleon Position



Background

In order to ensure consumer health products are safe and deliver the intended benefits, there are certain product types that have scientific, legal, or regulatory requirements to undergo research involving animals.

Technological advances mean that particular types of research can now be conducted using non-animal methods, such as computer modelling, studies using isolated cells or tissues, and *in vitro* (in a test tube, culture dish, or elsewhere outside a living organism) models. However, right now, these methods cannot always give the complete insight that scientists and regulatory authorities require into how a new product might affect biological systems.

This is why research using animal models can still be required. Humans are biologically similar to other mammals, hence researching certain products in animals provides a vital confirmation that they are safe and effective for human use. This is the same reason why many regulators make it a requirement that certain products are researched in animals prior to being used by humans.

As a purpose-led business focused on delivering better everyday health with humanity, we understand the strength of feeling and sensitivity around the use of animals in research. In this position, we set out our approach to the use of animals in research, our responsibilities to ensure high standards of care, welfare, and treatment for animals when no alternative method is feasible and testing is scientifically justified as well as longer-term commitments to reducing the future need for the use of animals in research.

What is our position?

Haleon is a global company with a unique portfolio of consumer health products, spanning non-prescription medicines, medical devices, cosmetics, and food and dietary supplements. Every year, millions of people trust Haleon with their everyday health due to the care we take in developing our products. People trust our brands because they know each product is grounded in trusted science and made with quality ingredients.

At present, animal studies may be the only method that can be used to evaluate the effects of a potential new healthcare product in a living system: whether to confirm intended benefit of the product; and/or to confirm the product is safe. Regulatory authorities around the world may require studies in animals before they will approve the use of a potential new product in clinical trials or license a new product for use in humans.

Animal studies represent a very small part of our research and development of innovative consumer healthcare products. We **only** use animals in the development of new products where alternative forms of testing do not exist, and where there is a specific scientific, legal or regulatory requirement to do so, in order to ensure our products are safe and deliver the intended health benefits. For almost 2 decades, we have committed to not conduct animal studies for cosmetic products where the primary purpose is aesthetic i.e., to improve the appearance of individuals and we have a zero-tolerance commitment to animal testing for cosmetic purposes.

Where we are required to use animals in research, all work is outsourced to third parties that have undergone an extensive vetting process (no animal testing is conducted in-house). The animal testing that is conducted is managed exceptionally sensitively with our maximum focus on ensuring it is done with the least number of animals and in the most humane way possible. All proposals for animal research are approved or rejected by our Chief Medical Officer. All animal study protocols are reviewed by a Haleon Animal Research Panel that includes a veterinarian specializing in laboratory animal medicine (animal welfare expert). Ultimately, we would like to see a future where the development of innovative products can be undertaken without the involvement of animals. We are committed to the replacement, reduction, and refinement of animal studies (the “3Rs”) in order to reduce, wherever possible, the proportion of new product development that involves animals.

In some areas, animal research is currently the only method that can be used to evaluate the effects of a potential new healthcare product in a living body, such as testing for carcinogenicity to ensure innovative products and treatments are safe for long-term use. Here it remains difficult to unlock viable alternative methods and identify suitable replacements in the foreseeable future.

However, we believe it may be possible to remove the involvement of animals entirely in *certain* areas of research, and we are committed to actively investigating alternative methods and approaches that will ultimately replace the use of animals.

Examples of our activities in the area of the 3Rs include:

- already adopted *in vitro* methods to address eye irritation, oral mucosal irritation, and skin irritation and sensitization without the use of animals;
 - ongoing initiative to investigate additional Skin Sensitization *In Vitro* Models to predict contact allergy;
- pioneered the use of alternative technology to demonstrate the availability of fluoride in toothpaste formulations to ensure efficacy against dental cavities without the use of animals. We have been investigating an alternative method for many years and are part of a group of companies actively engaging regulators to consider these alternatives;

- over the last 10 years, our Consumer Healthcare organisation has contributed more than £1.1M to animal alternative initiatives through collaboration with associations such as Cosmetics Europe and partner companies;
- pursued a project with the company Certara Inc. to develop a non-animal alternative model to predict exposure of diclofenac in human joints after topical dosing; and
 - Haleon signed a letter of commitment in Nov 2022 and joined *the International Collaboration on Cosmetics Safety* (ICCS). As a standing Board member with annual dues, Haleon supports the purpose of ICCS to advance the adoption of animal-free safety science for cosmetic products and ingredients through research, education, and regulatory engagement. Beyond research, ICCS will engage with regulators who will be critical to the acceptance and widespread deployment of new methods. Finally, ICCS will implement an educational program to build the capacity to utilize new approaches across the industry. The development and acceptance of new methods will have a global impact.

In summary, Haleon is committed to the 3Rs and we are actively engaged in efforts to develop and validate experimental methods that can provide alternatives to the use of animals in research.

Haleon is committed to move away from animal testing as soon as suitable alternative methods are available. For products that require regulatory submission, alternative methods that are validated and accepted by health authorities are always utilized. Where viable alternatives do not exist and we are required to use animals, we are fully committed to high standards (as detailed below) of humane care and treatment. This Haleon policy defines expected practices for the care, welfare, and treatment of research animals for all studies conducted on our behalf.

Our Commitments and Responsibilities

Reviews and Applied Governance

While part of GSK, the Consumer Healthcare business applied strict governance on the use of animals in research and managed its own rigorous assessment and approval process for animal studies. This subject matter expertise has been brought forward into Haleon following our separation from GSK. Haleon reviews the need for any animal study extremely carefully, either in the context of external regulatory requirements or by internal scientific and ethical review. These reviews are carried out by experienced Haleon scientists and with the oversight of external veterinary expertise.

Haleon has a risk oversight committee under the purview of the Chief Medical Officer where questions and/or issues related to the use of animals in research may be reported and subsequently addressed by qualified individuals.

Practicing the 3Rs

As detailed above, Haleon has several ongoing activities related to the 3Rs: Replace, Reduce, Refine. Any time we consider a need for the use of animals in research, we apply the 3Rs and through discussion, ethical debate and independent scientific review, our teams seek opportunities to replace animal studies wherever possible. We also aim to reduce the animal numbers required per study, and finally refine the study paradigm to reduce any potential pain and distress animals experience during our studies. We are committed to continue taking steps towards a future where the development of innovative consumer health products can be undertaken without the involvement of animals. In order to make progress, we are committed to continuing to invest in and drive research and partnerships to identify and unlock alternative methods and approaches that will ultimately mean animals are not used in our research.

Standards of Care

Haleon commits to high standards of care and treatment for all animals in our research. No animal testing is conducted in-house and every Haleon staff member involved in outsourcing animal testing is trained on our Policy and written standards on managing animal studies. We only engage experienced and reputable scientific partners to perform animal studies on our behalf who are AAALAC accredited and adhere to our animal policy and applicable laws. Haleon also has a process to perform a due diligence evaluation of these third parties. Additionally, we retain an expert veterinarian to ensure robust veterinary care programmes exist at all third parties where studies are conducted, and that third party facilities meet all applicable legal and regulatory requirements. All staff caring for animals at our scientific partners undertake specific training in animal welfare and these partners have veterinarians trained in laboratory animal medicine. Every scientific partner, irrespective of country location, must meet our principles on the care, welfare, and treatment of animals.

Types of Animals Used

Now and over the past decade, rodents have accounted for the vast majority of animals used in Haleon research. We never use Non-Human Primates.

All animals used for our studies are bred specifically for research. In addition, genetically altered animals (GAAs) (mice or rats) are only used when ethically and scientifically validated. The scientific partners that conduct studies on our behalf only purchase animals from commercial sources which have been inspected by

regulators, have undergone expert accreditation from bodies such as **AAALAC International**, and comply with our core principles on the care, welfare and treatment of animals.